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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,780	03/12/2004	Doris Hubler	PLOVIN-10	5621
23599 7590 11/15/2007 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER HUI, SAN MING R	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 11/15/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/798,780

Applicant(s)

HUBLER ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 7-19 and 26-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 20-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/10/04, 3/10/05, 1/12/06, 3/10/06, 4/16/07
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of the invention of group I, claims 1-6 and 20-25 in the reply filed on October 22, 2007 is acknowledged. The traversal is on the ground(s) that using other drugs in the herein recited method is considered a different method. This is not found persuasive because a composition and the related method is considered patentably distinct when the method can be practiced with a materially different product. In the instant case, the method of treating hypogonardism can be practiced with a different product and therefore the herein claimed composition and the method of using the same are patentably distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-19 and 26-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 22, 2007.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO95/12383 ('383) in view of Riffkin et al., Journal of Pharmaceutical Sciences, 1964, vol. 53, no. 8, p. 891-895), both references are of record.

'383 teaches an injectable solution comprising testosterone undecanoate, benzyl benzoate and a vegetable oil (See the abstract, also claims 1 and 2).

'383 does not expressly teach castor oil as one of the vegetable oil vehicle in the testosterone undecanoate injectable composition. '383 does not expressly teach the herein claimed ratio between castor oil and benzyl benzoate.

Riffkin et al. teaches that vehicle comprising castor oil and benzyl benzoate in a ratio of 1:1 or 65:35 as useful in delivering steroidal compounds for parenteral composition (See page 893 – 894, Table IV). Riffkin et al. also teaches that by adding benzyl benzoate into the composition would lower the viscosity of the composition and make the parenteral composition easy to be injected (See page 894, col. 1, first paragraph).

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate castor oil and benzyl benzoate, in the ratio herein claimed, in the parenteral composition containing testosterone undecanoate.

One of ordinary skill in the art would have been motivated to incorporate castor oil and benzyl benzoate, in the ratio herein claimed, in the parenteral composition containing testosterone undecanoate since castor oil, among other vegetable oils, is known to be suitable vehicles for injectable composition for steroids. Therefore, by adding benzyl benzoate and castor oil as a vehicle to the injectable testosterone

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undecanoate composition, one of ordinary skill in the art would be reasonably expected to be successfully formulate a parenteral intramuscular composition for testosterone undecanoate. Employing benzyl benzoate in a parenteral composition is reasonably expected to lower the viscosity and make the composition easier to be injected.

Furthermore, optimization of result effect parameters (e.g., range amount of the solvent employed) is obvious as being within the skill of the artisan.

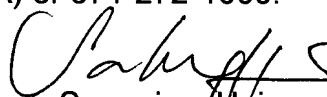
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



San-ming Hui  
Primary Examiner  
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